

### REMARKS

In the Office Action dated December 20, 2010, claims 1-3, 8, 9, 12, 13, 28-31 and 37 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of co-pending application Serial No. 10/549,211. Claims 1-3, 8, 9, 12, 28-30, 32-34, 37 and 38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro 6,039,754, in view of Cymbalisky 6,896,007. Claims 13 and 31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro and Cymbalisky in further view of Healy et al. 5,670,161 (Healy). Claims 35, 36, 39 and 40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro and Cymbalisky in further view of British Patent No. 2,298,577 to Angelini. For the reasons outlined in detail below, it is respectfully submitted that the pending claims are in condition for allowance over the art of record.

#### Double Patenting Rejection

Claims 1-3, 8, 9, 12, 13, 28-31 and 37 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-13 of copending application Serial No. 10/549,211. Because this is only a provisional obviousness-type double patenting, as the conflicting claims have not in fact been patented, applicant need not, and does not, at this point substantively respond to this rejection. If, and when, the subject matter of the '211 application issues into a patent, a substantive response to this rejection will be filed.

#### Independent Claim 1 and Dependent Claims 2, 8-13, 32 and 34-36

Claims 1, 2, 8, 9, 12, 32 and 34 were rejected as being unpatentable over Caro in view of Cymbalisky. Independent claim 1 now recites a graft for biomedical use,

wherein the graft is set such that the center line of the flow lumen follows a substantially helical path about a longitudinal axis so as to define a helical center line and wherein the flow tubing is flexible and is capable of adopting a configuration in which the longitudinal axis is curved and the helical center line of the tubing portion follows a substantially helical path about the curved longitudinal axis. Put another way, claim 1 has been amended to include the feature that the tubing is capable of adopting a configuration in which the longitudinal axis is curved and the helical center line of the tubing portion follows a substantially helical path about the curved longitudinal axis. This recitation is supported by the instant specification as filed, particularly at page 8, lines 4-5. It is also supported by originally filed claim 12.

In contrast, Cymbalisty only discloses a straight rigid pipe that extends linearly. In other words, the Cymbalisty pipe has a geometry that follows a helical path about a straight longitudinal axis. There is no teaching in Cymbalisty that the helical pipe geometry could be used in a pipe having a curved envelope. Indeed, Cymbalisty's slurry pipes are heavy duty pipes which would be made from steel or concrete and would not be capable of flexing into a curved condition. Moreover, in Cymbalisty, the travel of the slurry along the pipe takes place strictly due to gravity as is evident from, e.g., Figure 6. Therefore, curving the pipe or giving the pipe a curved envelope would not be advisable, as it would appear to interfere with the flow of the tar sands slurry or oil enriched middlings which are meant to be moved.

It was stated in the Office Action that Caro shows a curved graft. However, it is respectfully submitted that the curvature of the graft in Caro would not induce a person skilled in the art to utilize the Cymbalisty geometry except in a straight, longitudinal axis pipe or tube. Implementation of a geometry with a helical path that is curved around a

central longitudinal axis would require the non-obvious selection of particular geometrical features from each of Caro and Cymbalisty. In other words, it would require an unobvious modification of the Caro graft to introduce the flow lumen dimensions of Cymbalisty, but not the overall straight envelope that is taught in Cymbalisty.

Any such combination would, it is respectfully submitted, involve the use of impermissible hindsight. It would necessitate the use of applicant's own claims as a template into which the several unrelated teachings of Caro and Cymbalisty would need to be pasted. Should a person of skill in the art wish to modify Caro to have the geometry of Cymbalisty, which is disputed, such person would modify Caro to have a tubing following a helical path about a straight longitudinal axis because that is all which Cymbalisty teaches, and could be considered to teach. Again, Cymbalisty deals with rigid pipes and not flexible conduits, as pointed out in the Statement of Substance of Interview dated April 7, 2011

In view of the foregoing, it is respectfully submitted that pending claim 1 patentably defines over the asserted combination of Caro and Cymbalisty, as well as the remainder of the cited art.

Dependent claims 2, 8, 9, 12, 32 and 34 merely further patentably define the detailed subject matter of their parent claim or each other. As such, these claims are also believed to be in condition for allowance over the art of record.

As to claim 13, it is respectfully submitted that the teachings which are clearly absent in the combination of Caro and Cymbalisty are not provided by Healy. Therefore, even the asserted three-way combination of Caro, Cymbalisty and Healy does not render unpatentable pending claim 13.

Claims 35 and 36 were rejected as being unpatentable over Caro and Cymbalisty

in further view of Angelini. It is respectfully submitted that Angelini does not provide those teachings which are clearly absent from the two-way combination of Caro and Cymbalisty. Therefore, it is respectfully submitted that even the asserted three-way combination does not render claims 35 and 36 unpatentable. Neither does the remainder of the cited art.

#### Independent Claim 3 and Its Dependent Claims 28-31 and 33

Claims 3, 28-30 and 33 were similarly rejected in view of the two-way combination of Caro and Cymbalisty. As to claim 3, this claim recites a graft for biomedical use, wherein the graft is set such that the center line of the flow lumen follows a substantially helical path about a longitudinal axis so as to define a helical center line. The flow tubing of the graft is flexible and capable of adopting a configuration in which the longitudinal axis is curved and the helical center line of the tubing portion follows a substantially helical path about the curved longitudinal axis.

For the reasons outlined above in detail in connection with independent claim 1, it is respectfully submitted that claim 3 also patentably defines over the asserted combination of Caro and Cymbalisty. Moreover, claim 3 patentably defines over the remainder of the cited art as well.

Dependent claims 28-30 and 33 merely further patentably define the detailed subject matter of their parent claim. As such, these claims are also believed to be in condition for allowance over the asserted two-way combination, as well as the remainder of the cited art.

Claim 31 was rejected in view of the three-way combination of Caro, Cymbalisty and Healy. However, Healy does not provide those teachings which are clearly absent

from the combination of Caro and Cymbalistry. Therefore, claim 31 is also believed to be in condition for allowance over the asserted three way combination, as well as the remainder of the art of record.

#### Independent Claim 37 and Its Dependent Claims 38-40

Claims 37 and 38 were rejected over the two way combination of Caro and Cymbalistry. Claim 37 recites a graft for in vivo use comprising a flow tubing to carry blood and, which flow tubing is made of biocompatible material, the flow tubing being flexible and including a tubing portion with an internal diameter and defining a flow lumen. The flow lumen of the tubing portion includes a center line having a helix angle and a helix amplitude, the tubing portion being substantially free of ribs or grooves. The graft is shape set such that the center line of the flow lumen follows a substantially helical path, with a helix angle being less than or equal to  $45^{\circ}$  and with the amplitude of the helix being less than or equal to one half of the internal diameter of the tubing portion.

In sum, claim 37 has been amended to include the feature that the graft is shape set. There is ample support for the wording shape set in the original specification. In this connection, page 16, lines 20-22, discloses a method in which the tubular wall is set in a mandrel. Moreover, it is stated in the specification that the setting of the tubular wall is preferably carried out by a thermosetting process (see page 16, lines 34-35). There are additional disclosures in the specification of such thermosetting as well. Therefore, no new subject matter is being added.

It is noted that Cymbalistry is not and cannot be shape set due to the heavy duty nature of Cymbalistry's pipes. In other words, the material from which the Cymbalistry

pipes are manufactured would necessarily need to be cast in a helical shape at the outset, rather than being shape set into a helical shape. In addition, there is no disclosure in Caro of the graft being shape set.

Therefore, there is no teaching or disclosure in even the asserted combination of Caro and Cymbalisty of a graft which is shape set, such that the center line of the flow lumen follows a substantially helical path. In view of the foregoing, it is respectfully submitted that claim 37 patentably defines over the asserted combination of Caro and Cymbalisty. Moreover, claim 37 patentably defines over the remainder of the cited art as well.

Dependent claim 38 merely further patentably defines the subject matter of its parent claim. As such, this claim is also believed to be in condition for allowance.

Claims 39 and 40 were rejected over the three-way combination of Caro and Cymbalisty in further view of Angelini. However, Angelini does not supply those teachings which are clearly absent from the two-way combination of Caro and Cymbalisty. As such, claims 39 and 40 are also believed to be in condition for allowance over the three-way combination, as well as the remainder of the cited art.

#### New Dependent Claim 41

Newly submitted dependent claim 41 recites the feature that the graft comprises an ePTFE material. Support for this recitation is provided on page 14, at line 29. ePTFE or expanded polytetrafluoroethylene is a thermoplastic material which can be employed as a tubular material that can be shape set. In other words, the material will adopt a first shape and then, upon separation from the mandrel, adopt a second shape with a reduced helical amplitude (see the instant specification, page 16, line 35 to page

17, line 1). There is no teaching or disclosure of the claimed graft in any of the applied references to Caro, Cymbalisty, Healy or Angelini. Nor is there any such teaching to be found in the remainder of the cited art. Therefore, this claim is also believed to be in condition for allowance over the art of record.

New Dependent Claim 42

Applicant submits herewith new dependent claim 42 which depends from claim 37. Claim 42 recites that the graft comprises an ePTFE material. As noted, neither Cymbalisty or Caro disclose an ePTFE material. Moreover, the material ePTFE would not be suitable for the rigid pipes disclosed in Cymbalisty. The subject matter of claim 42 patentably defines over the asserted references, as well as the remainder of the cited art in any combination. As such, claim 42 is also believed to be in condition for allowance.

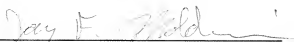
For the reasons outlined in detail above, it is respectfully submitted that the pending claims are in condition for allowance over the art of record. Such allowance is earnestly solicited.

Respectfully submitted,

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